K123415

biodenta®

MAR 1 9 2013

5

510(k) Summary

Owner's name:	Biodenta Swiss AG
Address:	Tramstrasse 16 9442 Berneck Switzerland
Phone:	+41 71 747 11 11
Fax number:	+ 41 71 747 11 12
Contact person:	Mr. David Eiler, Regulatory Manager
Date summary prepared:	Feb. 04, 2013
Trade / proprietary name:	Biodenta Dental Implant System – Bone Level Tapered
Common name:	Endosseous dental implant
Device classification name:	implant, endosseous, root-form
Product code:	DZE
Regulation number:	21 CFR 872.3640

Legally marketed device to which equivalence is claimed (predicate device):

1. Company:	Biodenta Swiss AG
Device name:	Biodenta Dental Implant System – Bone Level
510(k) number:	K111003
2. Company:	Keystone Dental
Device name:	Genesis Implant System
510(k) number:	K101545

K123415

biodenta®

Indications for Use:

Biodenta bone level tapered dental implants are intended for surgical placement in mandibles or maxillae to support single or multiple tooth restorations or terminal or intermediate abutment support for fixed or removable bridgework and to retain overdentures.

Device Description:

The Biodenta Dental Implant System – Bone Level Tapered is an integrated system of endosseous dental implants, which are designed to support prosthetic devices for partially or fully edentulous patients. The system consists of a variety of dental implants and related surgical instruments. The Bone Level Tapered implants use the same platforms and abutment connections like the Bone Level implants (K111003), and therefore the abutments and prosthetic parts of the Bone Level implants are used with the Bone Level Tapered implants.

The System includes dental implants with the following dimensions:
- Diameter 3.5 mm Implants with Length of: 8, 10, 12, and 14 mm; Platform B1
- Diameter 4.1 mm Implants with Length of: 8, 10, 12, and 14 mm; Platform B2
- Diameter 4.8 mm Implants with Length of: 8, 10, 12, and 14 mm; Platform B2
- Diameter 6.0 mm Implants with Length of: 8, 10, and 12 mm; Platform B2

Non-clinical Testing Data:

Fatigue testing was conducted according to FDA Guide: Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Guidance for Industry and FDA Staff and ISO 14801 Dentistry-Implants-Dynamic fatigue test for endosseous dental implants. The worst case scenario for the Biodenta Dental Implant System - Bone Level Tapered implants and abutments was tested. These results show that Biodenta Dental Implant System - Bone Level Tapered have sufficient mechanical strength for their intended clinical application.

Equivalence to marketed device:

Biodenta Swiss AG demonstrated that, for the purposes of FDA's regulation of medical devices, the Biodenta Dental Implant System - Bone Level Tapered is substantially equivalent to the predicate devices in intended use, material composition, fundamental scientific technology, principles of operation, and basic design.

K123415

biodenta®

Summary Substantial Equivalence Comparison to predicate devices:

	Subject Device	Predicate Devices	
Device Name	Biodenta Dental Implant System - Bone Level Tapered	Biodenta Dental Implant System – Bone Level (K111003)	Genesis Implant System (K101545)
Intended Use			
Intended use	Biodenta bone level tapered dental implants are intended for surgical placement in mandibles or maxillae to support single or multiple tooth restorations or terminal or intermediate abutment support for fixed or removable bridgework and to retain overdentures.	Biodenta bone level dental implants are intended for surgical placement in mandibles or maxillae to support single or multiple tooth restorations or terminal or intermediate abutment support for fixed or removable bridgework and to retain overdentures.	The Genesis Implant System is intended for use in single-stage or two-stage surgical procedures in all types of bone in partially or fully edentulous mandibles and maxillae. The Genesis Implant System supports single or multiple-unit restorations to re-establish patient chewing function and esthetics. Genesis implants are intended for placement following natural tooth loss or for immediate placement into an extraction socket. Immediate function may be achieved when good primary stability is established and appropriate occlusal loading is applied.
Basic Design			
Implant Type	threaded, root form, bone level implant	threaded, root form, bone level implant	threaded, root form, bone level implant
Implant Shape	Tapered	Straight	Tapered (+ straight types)
Implants Diameter (& Length)	3.5 mm (8 - 14 mm) 4.1 mm (8 - 14 mm) 4.8 mm (8 - 14 mm) 6.0 mm (8 - 12 mm)	3.5 mm (8 - 14 mm) 4.1 mm (8 - 14 mm) 4.8 mm (8 - 14 mm)	Tapered Implants: 3.8 mm (8.5 – 18 mm) 4.5 mm (8.5 – 18 mm) 5.5 mm (8.5 – 16 mm) 6.5 mm (8.5 – 13 mm) Straight Implants: 3.8 mm (8.5 – 18 mm) 4.5 mm (8.5 – 18 mm)
Implant to Abut. Connection	Internal Hexagon	Internal Hexagon	Internal 6 lobe
Material	Titanium Grade 4	Titanium Grade 4	Titanium Grade 4
Surface Treatment	Spark Anodization *(uses same surface modification as K111003)*	Spark Anodization	Double-acit-etching & Spark Anodization
Abutment System	Angled and Straight *(uses same abutments as K111003)*	Angled and Straight	Angled and Straight
Abutment Angle	0°, 15°	0°, 15°	0°, 15°
Sterilization (Implants)	Delivered Sterile Gamma Irradiation	Delivered Sterile Gamma Irradiation	Delivered Sterile Gamma Irradiation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 19, 2013

Mr. David Eiler
Regulatory Manager
Biodenta Swiss AG
Tramstrasse 16
Berneck, St. Gallen
Switzerland 9442

Re: K123415
Trade/Device Name: Biodenta Dental Implant System – Bone Level Tapered
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: February 14, 2013
Received: February 19, 2013

Dear Mr. Eiler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K123415

biodenta®

Indications for Use

510(k) Number (if known): K123415

Device Name: Biodenta Dental Implant System - Bone Level Tapered

Indications for Use:

Biodenta bone level tapered dental implants are intended for surgical placement in mandibles or maxillae to support single or multiple tooth restorations or terminal or intermediate abutment support for fixed or removable bridgework and to retain overdentures.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
2013.03.14
07:55:10 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123415